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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,508	03/26/2004	Xing Cheng	NS220US	8613
36577 7590 05/28/2008 JOHNATHAN KLEIN-EVANS ONE MEDIMMUNE WAY GAITHERSBURG, MD 20878			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,508	Applicant(s) CHENG ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,10-12,14-16,19,20,67,70-73 and 75-78 is/are pending in the application.
- 4a) Of the above claim(s) 71,73 and 77 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67,70 and 72 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,10-12,14-16,19,20,75,76 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and response filed March 14, 2008 is acknowledged and entered. Claims 1, 2, 4, 10-12, 14-16, 19, 20, 67, 70-76 and new claims 77-78 are pending. Claims 1, 2, 4, 10-12, 14-16, 19, 20, 67, 70, 72, 75, 76 and 78 are under examination with respect to SEQ ID NO: 1, 9 and 10, respectively, the elected sequences. Note that claims 71, 73 and 77 are withdrawn from consideration being drawn to non-elected subject matter, sequences other than SEQ ID NO: 1, 9 and 10. Objections/rejections of claims 71 and 73 are moot in view of the status of claims 71 and 73 being withdrawn from consideration as a result of Applicant's amendment.

Claims Summary and Interpretation

2. The claims are drawn to an isolated or recombinant nucleic acid molecule (DNA, cDNA, RNA or an artificial nucleic acid). The nucleic acid molecule comprises at least one artificially mutated nucleotide (deletion, insertion or substitution) relative to the polynucleotide sequence SEQ ID NO: 1. The nucleic acid molecule having the mutation is:

(a) a sequence that is greater than 97.8% identical to the full length SEQ ID NO: 1 or the full-length complement thereof, wherein the polynucleotide sequence encodes an infectious, replicating respiratory syncytial virus, or,

(b) a sequence encoding an amino acid sequence or unique subsequence selected from the group consisting of an amino acid sequence greater than 99.5% identical to SEQ ID NO: 9, and an amino acid sequence greater than 96.4% identical to SEQ ID NO: 10, wherein an RSV that comprises the amino acid sequence is infectious and replicating.

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Specifically, the nucleic acid molecule of (b) is at least 98.5% identical to SEQ ID NO: 1, or a complementary sequence thereof. The artificial mutation is located in the open reading frame encoding the polypeptide of SEQ ID NO: 10 (RSV M2-2 protein) or 12 (RSV G protein). Specifically the deletion in SEQ ID NO: 10 is a mutation of amino acid residue 1, 4, 10 or a combination thereof. In another embodiment, the open reading frame of SEQ ID NO: 10 or 12 is deleted. In another embodiment, amino acid residues 164-197 of SEQ ID NO: 12 are deleted.

The unique polynucleotide subsequence of the polynucleotide of (b) comprises at least one complete ORF, particularly SEQ ID NO: 9 and 10 (the elected embodiments).

Claim 67 is drawn to an isolated or recombinant nucleic acid comprising at least one artificially mutated nucleotide (deletion, insertion, substitution) relative to SEQ ID NO: 1, wherein the nucleic acid comprises at least one unique polynucleotide subsequence comprising at least 500 contiguous nucleotides of SEQ ID NO: 1 or a complementary sequence thereof. More specifically, the subsequence comprises at least 1000 contiguous nucleotides of SEQ ID NO: 1. In another embodiment, the subsequence comprises at least one polynucleotide subsequence from a different strain of virus, or at least one polynucleotide subsequence from a different strain of human RSV, or at least one subsequence from a different species of virus.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(*New Rejection*) Claims 1, 2, 4, 10-12, 14-16, 19, 20, 75, 76 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 1, 2, 4, 10-12, 14-16, 19, 20, 75, 76 and 78 recite, “An isolated or recombinant nucleic acid comprising at least one artificially mutated nucleotide relative to a polynucleotide sequence of SEQ ID NO: 1” [emphasis added]. “A” polynucleotide sequence of SEQ ID NO: 1 potentially refers to a fragment sequence of SEQ ID NO: 1. It is unclear whether Applicant intends a fragment of SEQ ID NO: 1, or “the” polynucleotide sequence of SEQ ID NO: 1, which means the full-length sequence of SEQ ID NO: 1. The metes and bounds of the claims cannot be clearly determined without further clarification.

Claims 14 and 15 are unclear because a sequence that is lacking the coding sequence for an entire reading frame (SEQ ID NO: 10 or 12) is not likely greater than 97.8% identical to SEQ ID NO: 1. Clarification is required.

Conclusion

4. Claims 67, 70 and 72 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 5-21-08
Primary Examiner, TC1600